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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by ANDREW M. CUOMO, Attorney General of the State of New York, and THE CITY OF NEW YORK, Plaintiffs, -against- MERCK & CO., INC., Defendant.	**No.: 07 cv 8434 (GBD)**

DEFENDANT MERCK & CO., INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO REMAND FOR LACK OF FEDERAL SUBJECT MATTER JURISDICTION

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Defendant Merck & Co., Inc. ("Merck") respectfully submits this memorandum in opposition to plaintiffs' Motion to Remand For Lack Of Federal Subject Matter Jurisdiction ("Motion to Remand").

ARGUMENT

As set forth in Merck's motion for stay, the Court should follow the course recommended by both the MDL Panel and the Vioxx MDL judge and defer consideration of plaintiffs' remand motion pending MDL transfer so that it can be considered in tandem with similar remand motions in six other state attorney general cases. However, if the Court does decide to rule on the remand motion prior to transfer, that motion should be denied because the claims in plaintiffs' complaint require resolution of two substantial federal questions and are thus removable under the Supreme Court's recent ruling in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing.*, 545 U.S. 308 (2005).

I. THE COURT SHOULD DEFER CONSIDERATION OF PLAINTIFFS' REMAND MOTION PENDING TRANSFER OF THIS CASE TO MDL 1657.

Both the MDL Panel and Judge Fallon, who is presiding over the Vioxx MDL proceeding in the Eastern District of Louisiana, have expressed their preference that overlapping remand motions be presented to the MDL court for coordinated treatment. Judge Fallon has explained:

> There are various issues of remand in various cases throughout the country. Again, a significant advantage of the MDL concept is some consistency. The Rule of Law is really based on consistency. If different decisions are made by numerous judges, then you have no consistency and no predictability. . . . It's easier if one court decides some of these matters than if 50 or 100 courts decide the matter.
>
> I'm conscious of dealing with the remand [motions] as quickly as possible, but I do want to get them all together . . . and deal with that issue in a consistent and fair fashion.

June 23, 2005 Status Conference Tr. at 21:9-22, *In re VIOXX Prods. Liab. Litig.*, MDL No. 1657 (attached to the November 9, 2007 Declaration of Vilia B. Hayes ("Hayes Decl.") as Exhibit A). *See also* Letter from JPML to Hon. Ricardo H. Hinojosa (Mar. 21, 2005) (Hayes Decl. Ex. B) ("wait[ing] until the Panel has decided the transfer issue . . . may be especially appropriate if the [remand] motion raises questions likely to arise in other actions in the transferee court and, in the interest of uniformity, might best be decided there if the Panel orders centralization").

Judge Fallon's concerns are consistent with the majority view –that the best way to ensure that MDL proceedings can achieve their statutory goal of efficient, coordinated proceedings is by staying litigation pending transfer to the MDL court, including the consideration of remand motions. Federal courts have overwhelmingly agreed, staying ***more than 3,400 Vioxx-related cases, including nearly 500 in which plaintiffs sought remand.*** As one court explained in granting a stay of a case that has now been transferred to the Vioxx MDL:

> [J]udicial economy and uniformity dictate that the Court defer ruling on Plaintiffs' Motion to Remand in order to . . . allow the MDL judge to resolve the issues presented by similar remand motions. . . . Judicial consistency, economy and uniformity among similar VIOXX cases would be served by deferring resolution of the remand issues at this time.

Fontanilles v. Merck & Co., Inc., No. 04-22799-CIV-HUCK, slip op. at 1-2 (S.D. Fla. Dec. 14, 2004) (Hayes Decl. Ex. C). *See also Alaska v. Merck & Co., Inc.*, No. 3:06-cv-0018-TMB, slip op. at 3 (D. Alaska Mar. 6, 2006) (Hayes Decl. Ex. D) ("transfer to the MDL [court] will promote efficient and coordinated proceedings, including the consideration of remand motions"); *Purcell v. Merck & Co., Inc.*, No. 05-443-L(BLM), slip op. at 4-5 (S.D. Cal. June 6, 2005) (Hayes Decl. Ex. E) (where "issue[s] common to several of the cases being considered for consolidation by the JPML [are presented in remand motions] . . . [b]y allowing a single court to determine this issue, judicial resources will be conserved and the risk of inconsistent rulings is

avoided") (citations omitted); *Lame Bull v. Merck & Co., Inc.*, No. Civ.S0524265 LKK/DAD, 2006 WL 194277, at * 2 (E.D. Cal. Jan. 24, 2006) ("[g]iven the number of cases that present this exact jurisdictional question and given the growing number of Vioxx cases being transferred to the MDL proceeding . . . this court follows the many other district courts in California in finding that the interest of judicial economy favors staying this action pending its transfer").

Deferral is particularly appropriate here because the MDL court already has before it six similar cases (five brought by state attorneys general and one by an alleged taxpayer on behalf of the state) that present the same jurisdictional issues. *See* Notice of Removal, *Foti ex rel. Louisiana v. Merck & Co. Inc.*, No. 05-3700 (E.D. La. Aug. 5, 2005)) (Hayes Decl. Ex. F); Notice of Removal, *Hood ex rel. Mississippi v. Merck & Co., Inc.*, No. 3:05-cv-666-HTW-JCS (S.D. Miss. Nov. 1, 2005) (Hayes Decl. Ex. G), now E.D. La. No. 05-6755); Notice of Removal, *Alaska v. Merck & Co., Inc.*, No. 3:06-cv-00018-TMB (D. Alaska Jan. 17, 2006) (Hayes Decl. Ex. H), now E.D. La. No. 06-3132; Notice of Removal, *Montana v. Merck & Co., Inc.*, No. CV 0607 H DWM (D. Mont. Mar. 1, 2006) (Hayes Decl. Ex. I), now E.D. La. No. 06-4302; Notice of Removal, *Utah v. Merck & Co., Inc.*, No. 2:06cv00406 (D. Utah May 18, 2006) (Hayes Decl. Ex. J), now E.D. La. No. 06-9336; Notice of Removal, *Franklin ex rel. Colorado v. Merck & Co., Inc.*, No. 06-CV-02164-WYD-BNB (D. Colo. Oct. 27, 2006) (Hayes Decl. Ex. K), now E.D. La. No. 07-2073 .

In all of these cases, the state attorneys general (or, in the case of Colorado, an alleged taxpayer on behalf of the state) seek damages and civil penalties for claimed misrepresentations made to the states and their citizens regarding Vioxx. *See generally id.* Furthermore, Merck has removed all of these cases on the same basis: that the state attorney general allegations, though

styled as state law claims, necessarily implicate federal law because of their entanglement with issues relating to federal food and drug and Medicaid law. *See generally id.*

In addition, there are currently motions to remand on the issue of federal question jurisdiction pending in the six Medicaid-related cases before the MDL court discussed above: *Utah*, No. 06-9336 (E.D. La.); *Hood*, No. 05-6755 (E.D. La.); *Foti,* No. 05-3700 (E.D. La.); *Montana*, No. 06-4302 (E.D. La.); *Alaska* , No. 06-3132 (E.D. La.); and *Franklin,* No. 07-2073 (E.D. La.).[1] The issue facing the Court here – the existence of federal question jurisdiction over such cases – is thus already in front of the MDL court.

Having the MDL court decide these cross-cutting jurisdictional issues will ensure that the various attorney general actions are treated in a uniform manner and that this Court does not enter a ruling that might ultimately be inconsistent with that of the MDL court on similar motions. *See In re Ivy*, 901 F.2d 7, 9 (2d Cir. 1990) (where "[t]he jurisdictional issue in question is easily capable of arising in [more than one court] . . . [c]onsistency as well as economy is . . . served [by transferring and consolidating cases as to which remand motions are pending]"); *see also Bd. of Trs. of the Teachers' Ret. Sys. v. WorldCom, Inc.*, 244 F. Supp. 2d 900, 905 (N.D. Ill. 2002) ("The question, then, is whether other courts are facing or are likely to face similar jurisdictional issues in cases that have been or may be transferred to a multidistrict proceeding."); *Benjamin v. Bayer Corp.*, No. 02-0886 Section: "R", 2002 U.S. Dist. LEXIS 9157, at *5 (E.D. La. May 16, 2002) ("because the issues involved in this remand are likely to be common to other transferred cases, the policies of efficiency and consistency of pre-trial rulings are furthered by a stay of the proceedings").

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1. In Merck's Reply Memorandum of Law in Further Support of its motion to stay, Merck stated that there were five such pending remand motions; in fact there are six.

In short, because the jurisdictional issues presented by plaintiffs' remand motion overlap with those in other state attorney general actions that have been transferred to the Vioxx MDL proceeding, the objectives of the MDL process – namely consistency and efficiency – will best be achieved by allowing the MDL judge to resolve these overlapping remand motions in a coordinated manner.

II. IF THE COURT CONSIDERS PLAINTIFFS' MOTION TO REMAND, IT SHOULD BE DENIED BECAUSE THE COURT HAS SUBSTANTIAL FEDERAL QUESTION JURISDICTION OVER THIS MATTER.

If the Court does consider the merits of plaintiffs' remand motion, it should be denied because the Court has substantial federal question jurisdiction over this case. The core of plaintiffs' claims is that Merck misrepresented the safety and efficacy of Vioxx, thereby inducing the state and its citizens to expend money on Vioxx as opposed to an alternative drug. (*See, e.g.*, Compl. ¶¶ 1, 6, 7, 8.) In order to assess the viability and merit of these allegations, a court will be required to intensely examine federal law, specifically the Food, Drug & Cosmetic Act ("FDCA"), which regulates drug manufacturers' public and promotional statements about prescription drugs; and federal Medicaid law, which determines both the drugs a state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. Because the claims at issue in this case depend on the resolution of questions of federal food and drug and Medicaid law, this Court has substantial federal question jurisdiction. *See Grable*, 545 U.S. at 311-12.

In *Grable*, the United States Supreme Court held that federal jurisdiction lies over "state law claim[s] [that] necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314. In so holding, the Supreme Court limited its prior opinion in *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986), by

making clear that a parallel federal private right of action is ***not*** necessary to establish federal question jurisdiction over state law claims.

Based on the *Grable* holding, a number of courts have denied plaintiffs' motions to remand in similar cases to this one. In *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), an MDL court asserted federal question jurisdiction over state-law claims involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid, finding that the case presented "a core of substantial issues [that were] federally oriented." *Id.* at 172-73. *See also West Virginia ex rel. McGraw v. Eli Lilly & Co., Inc.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (same). As shown below, plaintiffs' claims here present the very same dependency on federal law. Like the *Zyprexa* court, this Court should follow *Grable* and deny plaintiffs' motion to remand.

A. Resolution Of Plaintiffs' Claims Will Turn On Interpretations of Federal Statutes and Regulations, Including the Federal Food, Drug and Cosmetic and Medicaid Acts.

Plaintiffs' claims are premised on the allegation that Merck "caused false and fraudulent claims to be submitted to the [state Medicaid and EPIC] program by suppressing, misrepresenting and concealing material information in its communications with doctors and patients concerning the seriousness of the cardiovascular risks associated with Merck's drug Vioxx." (Compl. ¶ 1.) More specifically, plaintiffs allege that "[a]s a result of Merck's disinformation campaign . . . New York physicians wrote and continued to write prescriptions for Vioxx that they otherwise would not have written [and] those consumers would not have purchased and taken Vioxx, and third-party payors, including Medicaid, would not have paid for Vioxx." (*Id.* ¶ 8.) Plaintiffs seek, in part, to "obtain damages and restitution for the consumers and government agencies defrauded by Merck[.]" (*Id.* ¶ 9.) In order to assess these claims, a court would be required to navigate through interpretations of various federal statutes and

regulations, in particular, the complex body of law surrounding the federal FDCA and Medicaid statutes and regulations. Accordingly, federal law is substantially implicated by this lawsuit.

1. Federal Law Comprehensively Regulates The Public Statements That Underlie Plaintiffs' Claims.

First, federal food and drug law governs nearly every aspect of the types of public statements regarding Vioxx that form the basis of plaintiffs' allegations. Under the FDCA, the Food and Drug Administration ("FDA") is charged both with determining whether a drug is approved for use by humans and with assessing the specific uses for which that drug may be administered. 21 U.S.C. §§ 331(a), (d), 355; *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000). As part of the federal regulatory scheme, the FDA's Center for Drug Evaluation & Research ("CDER") regulates prescription drug advertising, including the package inserts that outline benefit and risk information, and also monitors marketed drugs for unexpected health risks that may require public notification, a labeling change, or removal of the drug from the market.[2] Under federal law, even the claims made in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4).[3] Thus, the marketing, testing, labeling, and approval of Vioxx – the very issues that form the basis of plaintiffs' complaint – were all governed by federal law. (*See, e.g.,* Compl. ¶¶ 2, 29, 30 (allegations related to FDA oversight of Merck's Vioxx-related activities).)

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2. *See* Center for Drug Evaluation and Research, *Frequently Asked Questions to CDER*, Sept. 19, 2002, http://www.fda.gov/cder/about/faq/default.htm.

3. Furthermore, the FDA recently promulgated a final rule in which it stated that "FDA approval of labeling under the [FDCA] . . . preempts conflicting or contrary State law," in part because "[S]tate law requirements can undermine safe and effective [drug] use." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934-35 (Jan. 24, 2006) (to be codified at 21 C.F.R. Parts 201, 314, and 601).

2. Plaintiffs' Claims Implicate Significant Issues Pursuant to the Federal Medicaid Program.

Second, plaintiffs' complaint raises substantial disputed federal issues under federal Medicaid law because it depends on the interpretation and application of federal statutory provisions that govern what drugs must be covered by or can be excluded from all state Medicaid drug reimbursement programs, including New York's Medicaid drug reimbursement program.

There can be no doubt from the face of the complaint that plaintiffs expressly claim damages for their Medicaid-related expenditures for Vioxx. (*See, e.g.*, Compl. ¶¶ 1, 76.) The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 430.10, *et seq.* In addition to providing federal money for Medicaid drug programs, federal law also determines and controls the method by which states can administer those programs. As the Supreme Court has noted, "[a]lthough participation in the program is voluntary, participating States must comply with certain requirements imposed by the [Act] and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990). One of the primary requirements that the federal Department of Health and Human Services has instituted is that states designate "a single State agency . . . to administer or supervise the administration of the [Medicaid] plan… ." 42 C.F.R. § 431.10(b)(1). Accordingly, the state of New York has designated its State Department of Health to administer its Medicaid plan. *See* New York State Dep't of Health, Medicaid in New York State, *http://www.health.state.ny.us/health_care/medicaid/index.htm.* (*See also* Compl. ¶ 14.)

Federal law also defines what constitutes a "covered outpatient drug" under a state's Medicaid program, *i.e.*, a drug "which may be dispensed only upon prescription" and "which is approved for safety and effectiveness as a prescription drug under" the FDCA. 42 U.S.C.

§1396r-8(k)(2)(A)(i). And federal law expressly requires states, subject to certain narrow exceptions, to reimburse the "covered outpatient drugs" of any manufacturer that has entered into and complies with a rebate agreement with the federal Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B). In fact, the only time that a state can exclude from its Medicaid formulary a covered outpatient drug subject to a rebate agreement is "if, based on the drug's labeling . . . the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment . . . over other drugs included in the formulary . . . ." 42 U.S.C. § 1396r-8(d)(4)(C). But even then, a state cannot deny coverage altogether; rather, it must condition such reimbursement on prior authorization, meaning that the state may require that it approve its reimbursement of the drug prior to dispensation. 42 U.S.C. § 1396r-8(d)(4)(D). And even a decision to require prior authorization is subject to other federal requirements, *see* 42 U.S.C. § 1396r-8(d)(4)(E), (d)(5), and, pursuant to federal statute, must be in writing, 42 U.S.C. § 1396r-8(d)(4)(B).[4] Thus, every step that a state like New York takes with regard to coverage of an FDA-approved drug under its Medicaid program is subject to strict federal mandates.

Here, plaintiffs' complaint, which seeks compensation for money that they paid for Vioxx, while brought under a state law theory, is entwined with federal Medicaid law and regulations, further confirming that substantial federal question jurisdiction exists over this case.

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4. The New York Medicaid Program is inextricably tied to the federal Centers for Medicare & Medicaid Services ("CMS") in the Department of Health and Human Services, as the CMS is directed to approve all state Medicaid plans and proposed amendments based on the state's compliance with federal Medicaid law. 42 C.F.R. § 447.256. *See also* 42 C.F.R. § 430.14 (CMS "reviews State plans and plan amendments, discusses any issues with the [state] Medicaid agency, and consults with central office staff on questions regarding application of Federal policy."); 42 C.F.R. § 430.12 (outlining mandatory procedures State must follow when submitting a proposed state Medicaid plan or state Medicaid plan amendment for CMS's approval). For example, CMS authorization was required before New York (and other states) could participate in a multi-state pooling agreement for the purchase of Medicaid prescription drugs. *See* U.S. Dep't of Health & Human Services, Centers for Medicare & Medicaid Services, States with Supplemental Rebate Agreements, *http://www.cms.hhs.gov/MedicaidDrugRebateProgram/17_SRAStateChart.asp* (chart listing states that participate in a multi-state pooling supplemental rebate agreement).

B. The Supreme Court's *Grable* Decision Makes Clear That Federal Jurisdiction Lies Over Claims Like Plaintiffs' That Turn On Significant Questions Of Federal Law.

The Supreme Court's *Grable* decision, which clarifies the scope of substantial federal question jurisdiction, confirms that this case was properly removed to federal court. In *Grable*, the United States Supreme Court held that federal jurisdiction lies over "state-law claim[s] [that] necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314. The Court further stated unequivocally:

> [T]his Court ha[s] recognized for nearly 100 years that in certain cases ***federal question jurisdiction will lie over state-law claims that implicate significant federal issues***. The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.

Id. at 312 (internal citation omitted) (emphasis added). The *Grable* court also clarified the Supreme Court's prior opinion in *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986). Over the last two decades, courts have interpreted *Merrell Dow* to hold that substantial federal question jurisdiction exists only when the federal law implicated by the state-law claims provides a private right of action. In *Grable*, however, the Court explicitly rejected that interpretation of *Merrell Dow*, explaining that while the provision of a federal private right of action can be evidence of whether Congress intended for there to be a federal forum, the key question, as stated above, is whether the "state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314.

Grable confirms that this Court has federal question jurisdiction over plaintiffs' claims for two reasons. ***First***, because plaintiffs' claims turn directly on Merck's heavily regulated marketing of Vioxx (*see* Compl. ¶ 30 ("the February 2001 [FDA] Advisory Committee found that physicians needed clear information, including the data from VIGOR, about Vioxx's serious cardiovascular risks in order to make appropriate treatment judgments for their patients. The FDA concurred in this judgment[]")), "the propriety of [the defendant's] actions, as prescribed under federal law . . . is at the heart of [the plaintiffs'] allegations." *D'Alessio v. N.Y. Stock Exch., Inc.*, 258 F.3d 93, 102-103 & n.6 (2d Cir. 2001) (finding federal jurisdiction because state law tort claims were "predicated on alleged breaches of" federal securities law by defendants); s*ee also Brennan v. Southwest Airlines Co.*, 134 F.3d 1405, 1409 (9th Cir. 1998) (denying remand where plaintiffs pleaded only state-law causes of action expressly, and the substance of plaintiffs' suit arose under federal law); *Nat'l Credit Reporting Ass'n v. Experian Info. Solutions, Inc.*, No. C 04-01661 WHA, 2004 U.S. Dist. LEXIS 17303, at *7 (N.D. Cal. July 21, 2004) ("A claim raises a substantial federal question when its resolution requires reference to or interpretation of federal law."). *See also Drawhorn v. Qwest Commc'ns Int'l, Inc.*, 121 F. Supp. 2d 554, 564 (E.D. Tex. 2000) (holding that federal question jurisdiction exists where "the interpretation of the federal statutes . . . is a necessary and substantial part of the plaintiff's own causes of action").[5]

Second, as discussed above, the Court will be required to interpret federal Medicaid law in assessing the validity of plaintiffs' claims. Specifically, the Court will need to determine

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5. The State should not be allowed to avoid federal question jurisdiction merely because, as it states in the Motion to Remand, "[T]his action alleges violations solely of state and local law[.]" (Pls.' Mem. at 1.) What matters, as *Grable* and even pre-*Grable* cases such as *Southwest Airlines Co.* make clear, is whether plaintiffs' state law claims turn on the resolution of a question of federal law – not whether plaintiff explicitly cites those federal laws in the complaint.

whether New York was required to include Vioxx on its Medicaid formulary because, under the federal statutory and regulatory provisions, it was a "covered outpatient drug," thereby "dispensed only upon prescription" and "approved for safety and effectiveness" pursuant to the FDCA, and thus subject to a rebate agreement between Merck and the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B), (k)(2)(A). And, as noted above, New York could have excluded Vioxx from its Medicaid formulary "only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs included in the formulary." 42 U.S.C. § 1396r-8(d)(4)(C).[6]

The applicability of *Grable* in these circumstances was recognized by an MDL court that denied a motion to remand under similar circumstances. In *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court relied on *Grable* in asserting federal question jurisdiction over state-law claims involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid. As in this case, the complaint in *Zyprexa* purported to state claims under state law based on alleged conduct regulated by the FDA. *Id.* at 172. The core allegation was that the manufacturer of the prescription drug Zyprexa marketed the drug for off-label or non-FDA-approved uses, which caused the Louisiana Department of Health and Hospitals to wrongfully disburse Medicaid funds to pay for Zyprexa prescriptions and the resulting Zyprexa-related injuries. *Id.* at 170-72. The MDL court applied *Grable* and retained federal jurisdiction because of the "substantial federal funding provisions involved" and because allegations that the manufacturer had improperly

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6. For this reason, *New York v. Lutheran Center For The Aging*, 957 F. Supp. 393 (E.D.N.Y. 1997), which plaintiffs argue defeats Merck's argument that substantial Medicaid issues are necessary to plaintiff's claims (Pls.' Mem. at 18-19), is not relevant. In that case, no such federal requirement was at issue. *Id.* at 400 ("The State is 'solely responsible for establishing eligibility requirements for recipients.'").

marketed Zyprexa for non-FDA-approved uses rendered the case "federally oriented." *Id.* at 172-73.

The same federal funding provisions are integral here,[7] as is the question of whether the federally-regulated marketing activities surrounding Vioxx involved misrepresentations. Plaintiffs' attempt to distinguish *Zyprexa* on the grounds that they do not allege that Merck violated federal law (Pls.' Mem. at 16) fails because notwithstanding their attempts to avoid citing the FDCA in their complaint, plaintiffs' allegations do depend on proving violations of that statute. Thus, the interrelation between plaintiffs' allegations and federal FDCA and Medicaid program requirements make this case equally "federally oriented." *Id.*

Likewise, in *McGraw*, the Eastern District of New York denied a similar motion to remand, finding that "[r]esolution of the question of the state's obligation to reimburse its insureds for Zyprexa, using funds largely provided by the federal government, is essential to the state's theory of damages and presents a substantial and disputed federal issue under *Grable.*" 476 F. Supp. 2d at 233. The very same federal questions are involved in assessing plaintiffs' claims here.

Similarly, in another case involving Medicaid drug pricing, the court in *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005) held that federal jurisdiction was proper under *Grable*. In concluding that the allegations that defendants had overcharged plaintiff for Medicaid drugs implicated substantial questions of federal law, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." *Id.* at

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7. For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 50% of New York's Medicaid financing. *See Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2003 Through September 30, 2004*, 67 Fed. Reg. 69,223, 69,224 (Nov. 15, 2002).

1027. The court noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Id.* As discussed *supra*, the federal questions implicated here "impact [two] complex federal regulatory scheme[s]." And, for the same reasons explained *supra*, plaintiffs' attempt to distinguish this case on the grounds that they do not allege that Merck violated federal statutes fails.

For all of these reasons, the Court should conclude that federal question jurisdiction exists here under the reasoning of *Grable*.

III. PLAINTIFFS' ARGUMENTS IN SUPPORT OF REMAND FAIL.

In arguing against federal jurisdiction, plaintiffs principally make two arguments. First, plaintiffs argue that Merck's removal notice was not sufficiently specific. Second, plaintiffs attempt to rely on cases where courts remanded cases that were removed under federal question jurisdiction. Both arguments fail.

First, plaintiffs' argument that remand is required because in its Notice of Removal, Merck "failed to identify any specific issues of federal law" (Pls.' Mem. at 6) is simply a red herring. Notably, plaintiffs do not explain what precisely they found lacking, and "[t]he absence of detailed grounds setting forth basis for removal is not fatal to defendants' right to remove." *Allman v. Hanley*, 302 F.2d 559, 562 (5th Cir. 1962). As the United States Court of Appeals for the Second Circuit put it, "[t]he modern rules of notice pleading 'apply with as much vigor to petitions for removal as they do to other pleadings, which, according to Rule 8(f), F. R. Civ. P. shall be so construed as to do substantial justice.'" *White v. Wellington*, 627 F.2d 582, 587 (2d Cir. 1980) (quoting *Rachel v. Georgia*, 342 F.2d 336, 340 (5th Cir. 1965), *aff'd* 384 U.S. 780 (1966)). By this liberal standard, Merck's Notice of Removal was more than sufficient. As

explained in Section II.A. *supra*, and in Merck's Notice of Removal (*see* Notice of Removal ¶¶ 11-20 (explaining how liability depends on whether Merck violated the federal FDCA and the federal Medicaid Act, along with the regulations promulgated by federal agencies to implement them)), Merck has provided ample jurisdictional grounds for removing this action because it identified two substantial disputed federal questions that must be resolved to determine liability on the claims asserted in plaintiffs' complaint.

Second, plaintiffs rely on a series of cases involving federal questions of far less significance to resolution of the claims at issue in those cases than the federal questions at issue here. Accordingly, plaintiffs' cases are irrelevant to the Court's remand analysis and do not refute applicability of *Grable*, *Zyprexa*, *McGraw*, and *Astra USA* to plaintiffs' claims.

For example, plaintiffs rely on *Empire Healthchoice Assurance, Inc. v. McVeigh*, --- U.S. ---, 126 S. Ct. 2121 (2006) (*see* Pls.' Mem. at 7) to argue that *Grable* applies only to a very few cases, and that this is not one of them. In *Empire*, however, the Court declined to apply *Grable* because the underlying factual basis for the claim "was triggered, not by the action of any federal department, agency or service, but by the settlement of a personal-injury action launched in state court[.]" 126 S. Ct. at 2137. Here, the FDA's approval of Vioxx with mandatory labeling and concomitant regulation of marketing activities is precisely what plaintiffs allege caused them injury. Additionally, plaintiffs' reliance on *Merrell Dow* and *Franchise Tax Board of California v. Construction Laborers Vacation Trust for Southern California*, 463 U.S. 1 (1983) to argue that allowing federal question jurisdiction here would undermine comity and federalism, resulting in "opening the federal court doors to a huge influx of state law personal injury, fraud, and Medicaid cases" is unpersuasive. (*See* Pls.' Mem. at 7-9, 18.) This is not a case where the only issue in play is whether Merck violated a federal standard. Nor, contrary to plaintiffs'

implication, is it a case where Merck asserts that simply because it has a defense under federal law, the case belongs in federal court. (Pls.' Mem. at 5.) Instead, as explained above, entire complex regulatory schemes administered by two separate federal agencies are implicated, and a need for national uniformity in interpretation of those schemes mandates federal jurisdiction here. *See McGraw*, 476 F. Supp. 2d at 234 (finding substantial federal question jurisdiction where "an intricate federal regulatory scheme including detailed federal funding provisions, requiring some degree of national uniformity in interpretation" was implicated by plaintiff's state-law claims).

In addition, in several of the cases cited by plaintiffs, the federal question at issue was limited to the meaning of the phrase "'average wholesale price' as it appears in the Medicare statute and its implementing regulations." *Wisconsin v. Abbott Labs.*, 390 F. Supp. 2d 815, 823 (W.D. Wis. 2005); *see also In re Pharm. Indus. Average Wholesale Price Litig. v. Abbott Labs.*, MDL No. 1456, No. 01-12257-PBS, 2007 U.S. Dist. LEXIS 68193 (D. Mass. Sept. 17, 2007), *Pennsylvania v. Tap Pharm. Prods., Inc.*, No. 2:05-CV-03604, 2005 WL 2242913 (E.D. Pa. Sept. 9, 2005), *Minnesota ex rel. Hatch v. Pharmacia Corp.*, No. 05-1395(PAM/JSM), 2005 U.S. Dist. LEXIS 27638 (D. Minn. Oct. 22, 2005), *Missouri ex rel. Johnson v. Mylan Labs., Inc.*, No. 4:06CV603 HEA, 2006 U.S. Dist. LEXIS 32570 (E.D. Mo. May 23, 2006), *Hawaii v. Abbott Labs, Inc.*, 469 F. Supp. 2d 842 (D. Haw. 2006) (Pls.' Mem. at 12, 19). Here, in contrast, plaintiffs' claims implicate two huge legal and regulatory frameworks that govern every aspect of the approval, labeling, and marketing of drugs, as well as coverage of FDA-approved drugs by state Medicaid programs. *See, e.g., Zyprexa*, 375 F. Supp. 2d at 172-73 (federal jurisdiction appropriate with regard to Medicaid and the marketing and labeling of a drug); *McGraw*, 476 F. Supp. 2d at 234 (*Hawaii* distinguished because the federal question presented in Medicaid

reimbursement claim involving alleged misrepresentations about drug "extend beyond the definition of a single federal statutory term to encompass a broad range of federal regulatory and funding provisions").

Moreover, the remand orders in *Wisconsin*, *Tap Pharmaceutical*, and *Minnesota* were also based on the fact that the removal was ***procedurally*** defective in those cases, thereby requiring remand. *Wisconsin*, 390 F. Supp. 2d at 824-25; *Tap Pharm.*, 2005 WL 2242913, at * 9; *Minnesota*, 2005 U.S. Dist. LEXIS 27638, at * 8. Notably, another district court rejected a plaintiff's reliance on *Wisconsin* for this very reason, finding that "removal had been procedurally defective and provided an independent and adequate reason to remand to state court." *Astra USA, Inc.*, 401 F. Supp. 2d at 1031 (rejecting *Wisconsin*'s interpretation of *Grable* and concluding that the significant dependence on federal Medicaid law of pricing allegations supported federal jurisdiction).

Plaintiffs' reliance on the decisions to remand in *Texas v. Merck & Co., Inc.*, 385 F. Supp. 2d 604 (W.D. Tex. 2005); No. A-06-CA-232-LY slip op. (W.D. Tex. May 10, 2006) (Pls.' Mem. at 12-13) is not persuasive either. As explained in Section I *supra*, that court's decision to remand is clearly at odds with the majority view. In other state attorney general actions involving Vioxx, courts have stayed all proceedings on the grounds that the cases are best coordinated in the MDL court, or otherwise declined to rule on remand motions prior to the transfer of the cases to MDL-1657. And the *Texas* court's explanation that "[t]here is no serious federal interest in claiming the advantages thought to be inherent in a federal forum" (*Texas*, slip op. at 6) ignores the intricate statutory and regulatory schemes inherent in FDCA and Medicaid law. Moreover, as explained in *McGraw*, the need for national uniformity in interpretation of disputed federal questions surrounding plaintiffs' damages claims under Medicaid is best met by

resolving them in a federal judicial form, not multiple state-law regimes. *See McGraw*, 476 F. Supp. 2d at 234 ("detailed federal [Medicaid] funding provisions, requiring some degree of national uniformity in interpretation" confer substantial federal question jurisdiction).

Plaintiffs' other cases are inapposite for various reasons. *Barash v. Ford Motor Credit Corp.*, No. 06-CV-6497 (JFB) (ARL), 2007 U.S. Dist. LEXIS 44641 (E.D.N.Y. June 20, 2007) involved a *pro se* plaintiff who, while asserting state-law fair credit claims cited analogous federal cases interpreting the Fair Credit Reporting Act ("FCRA"). *Id.* at *12-13. The court found that no federal question was raised by plaintiffs' complaint because he sued under a state analog to the federal FCRA. *Id.* at *13. That is not the case here. *Barbara v. New York Stock Exch*ange, 99 F.3d 49 (2d Cir. 1996) is inapposite because it relied on *Merrell Dow's* focus on whether a federal private right of action is provided in the federal scheme. *Id.* at 54 ("[t]he lack of a private right of action counsels against a finding of federal question jurisdiction"). As explained above, *Grable* clarified that such a focus is not dispositive. *Caggiano v. Pfizer Inc.*, 384 F. Supp. 2d 689 (S.D.N.Y. 2005) is distinct because the Medicaid-related issues that must necessarily be determined to find Merck liable in this action were not at issue there.

In short, none of plaintiffs' cases supports remand under these circumstances. Despite plaintiffs' arguments to the contrary, this matter clearly implicates two very substantial federal questions – the FDCA and federal Medicaid law – and, under the Supreme Court's *Grable* decision, the Court plainly has jurisdiction to resolve these substantial federal questions in a federal forum.

CONCLUSION

For all of the foregoing reasons, Merck respectfully requests that the Court defer consideration of plaintiffs' Motion to Remand pending MDL transfer. Alternatively, if the Court does rule on the merits of plaintiffs' remand motion, it should be denied.

DATED: New York, New York
November 9, 2007

Respectfully submitted,

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